

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Milbemycin Oxime Solution

AGENCY: Food and Drug Administration, HHS.

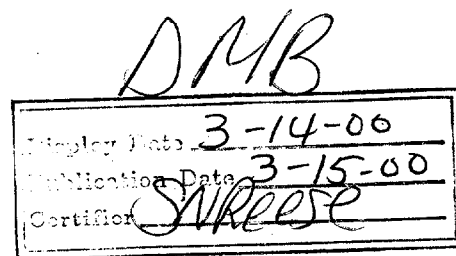
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for veterinary prescription use of milbemycin oxime solution to treat ear mite infestations in cats and kittens 8 weeks of age and older.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419-8300, filed NADA 141-163 that provides for veterinary prescription use of MILBEMITE™ Otic Solution (0.1 percent milbemycin oxime) for the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens 8 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite. The NADA provides for use of one 0.25-milliliter tube per ear as a single treatment. NADA 141-163 is approved as of February 2, 2000, and the regulations are amended in 21 CFR part 524 by adding new § 524.1446 to reflect the approval. The basis of approval is discussed in the freedom of information summary.



In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for non-food-producing animals qualifies for 3 years of marketing exclusivity beginning February 2, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

FDA has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1446 is added to read as follows:

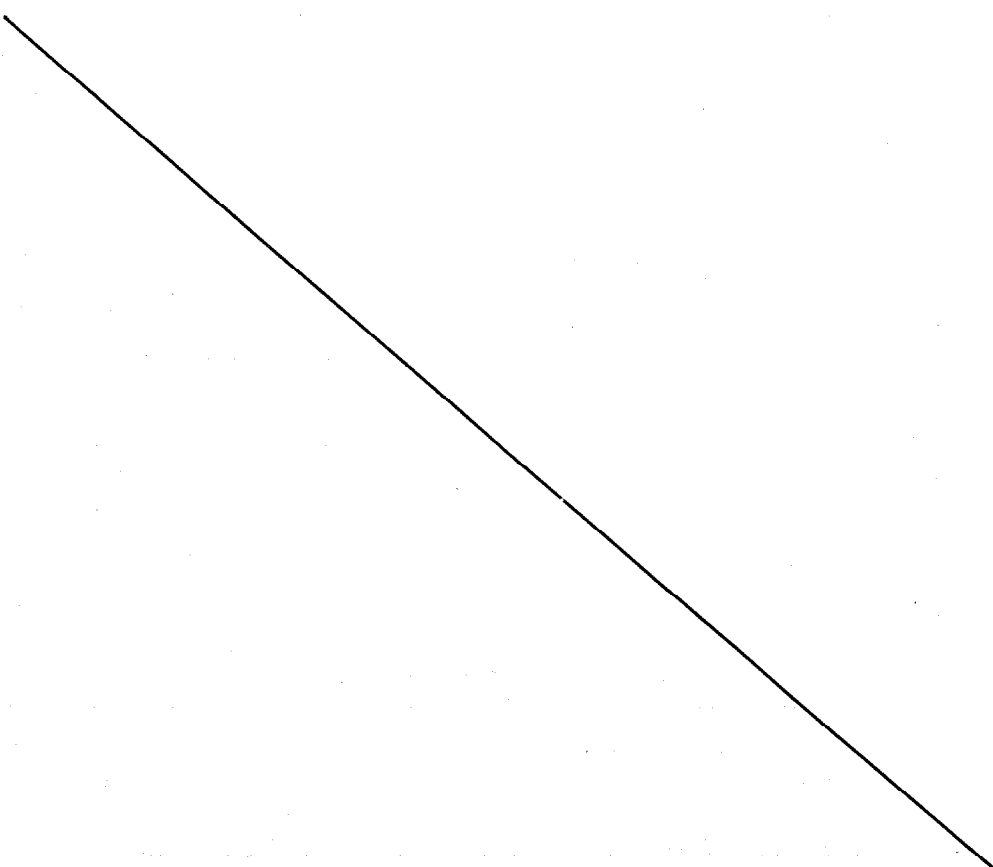
§ 524.1446 Milbemycin oxime solution.

(a) *Specifications.* Each tube contains 0.25 milliliter of a 0.1 percent solution of milbemycin oxime.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One tube administered topically into each external ear canal as a single treatment.

(2) *Indications for use.* For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens 8 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.



(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 3/2/00
March 2, 2000

S F S
Stephen F. Sundlof

Director
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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